

Appl. No. 10/053,302  
Amendment dated June 24, 2004  
Reply to Office Action of February 25, 2004

### REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the rejections of the claims.

Applicants have canceled claims 4, 11 and 12 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these claims in one or more continuation applications.

Claims 1, 8-11, and 14 have been amended. Claim 1 has been amended to correct obvious typographical errors, and claim 8 has been amended to provide greater clarity. Claims 9-11 and 14 have been amended to change the dependencies of these claims. Applicants submit that the amendments to the claims are supported throughout the specification and originally filed claims and do not raise any issues of new matter.

Applicants have amended the specification to update the priority information. Applicants have also amended the specification to add the deposit numbers and dates of deposit of the deposited material. Applicants submit these amendments do not raise any issues of new matter.

### Petition for Extension of Time

It is noted that a one-month petition for extension of time is necessary to provide for the timeliness of the response. A request for such an extension is made extending the time for response from May 25, 2004 to June 25, 2004.

### Claim for Priority

Applicants note that the Examiner has requested that all 119 and 120 information be inserted on first page of the application. Applicants note that in the transmittal documents, Applicants made a claim for priority and requested that the specification be amended by inserting before the first line:

"This is a continuation of Application Serial No. 09/166,298 filed October 5, 1998, which claims benefit of Application Serial No. 60/061,185 filed October 6, 1997, abandoned, both of which are hereby incorporated by reference."

Appl. No. 10/053,302  
Amendment dated June 24, 2004  
Reply to Office Action of February 25, 2004

Applicants submit that they have properly established a claim for priority. Applicants resubmit this amendment herein and request that the Examiner confirm entry of this amendment to the specification and acknowledge the claim for priority.

### Provisional Double Patenting Rejection

The Examiner provisionally rejects claims 1-11 and 14 for nonstatutory double patenting over claims 1-5, 13-15, and 20-22 of copending Application No. 08/943,771. The Applicants will consider submitting a terminal disclaimer if necessary upon notice of allowable subject matter.

### 35 U.S.C. 112, first paragraph

Claims 3 and 4 are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The Examiner asserts the scope of the claims exceeds the enablement of the specification. Applicants have canceled claim 4 rendering this rejection moot. The Applicants respectfully traverse this rejection with respect to claim 3.

In order to make a rejection, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993); MPEP §2164.04. "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis [enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971); MPEP §2164.04. Further, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); MPEP §2164.01.

Applicants respectfully assert that the Examiner has not provided a reasonable basis to reject claim 3 under 35 U.S.C. §112, first paragraph. The Examiner bases his rejection upon his belief that all six of the CDRs from both the V<sub>L</sub> and V<sub>H</sub> domains are required for binding an epitope. The Examiner asserts the following:

Antibodies are useful because they specifically bind to epitopes on antigens. The minimal structure for binding to an epitope is the 6 CDR's found in the light and heavy chain variable region. *Since* Applicant's claim read on less than the required structure to specifically bind the antigen, they are not enabled for the full

Appl. No. 10/053,302  
Amendment dated June 24, 2004  
Reply to Office Action of February 25, 2004

scope of the claimed invention. [*emphasis added*] Office Action (Feb. 25, 2004)  
at p. 2.

The Examiner has not provided any evidence that *all of the CDRs* of the  $V_L$  and  $V_H$  are required for antigen binding, other than an unsupported conclusory statement. Applicants respectfully submit that the minimal structure for binding to an antigen can be less than all six of the CDRs. The instant application teaches that a single variable domain, either the  $V_L$  or  $V_H$  domain, is sufficient for binding.

[E]ven a single variable domain (or half of an Fv comprising only three CDRs specific for an antigen) has the ability to recognize and bind antigen, although at a lower affinity than the entire binding site. Specification at p. 8, lines 18-20.

The Examiner has not provided any evidence to contradict the teaching of the specification and has not established a reasonable basis for an enablement rejection of claim 3. Applicants submit that it is known to those of skill in the art that a single variable domain is capable of binding to an antigen. One example of such antibodies is the camelid monobodies, which are comprised of only a heavy chain and can readily bind antigen.

Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 3 under 35 U.S.C. §112, first paragraph.

Claims 1-11 and 14 are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The specification has been amended to include the American Type Culture Collection (ATCC) Accession numbers for the hybridomas that produce the 3B7, 1F3, and 1D3 antibodies and dates of deposit. At page 79 of the specification, Applicants confirm that the deposits were made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure and Regulations. Applicants further state that the hybridomas will be irrevocably and without restriction or condition released to the public upon the issuance of the U.S. patent.

These cell lines will be made available by ATCC under the terms of the Budapest Treaty, and subject to an agreement between Genentech, Inc. and ATCC, which assures permanent and unrestricted availability of the cell lines to the public upon issuance of the pertinent U.S. patent... page 79, lines 4-6.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 1-11 and 14 under 35 U.S.C. §112, first paragraph.

Appl. No. 10/053,302  
Amendment dated June 24, 2004  
Reply to Office Action of February 25, 2004

### Conclusion

In view of the foregoing, the Applicants believe that all claims as currently pending are in condition for allowance and such action is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

Date: June 24, 2004

Katherine M. Kowalchyk  
Katherine M. Kowalchyk  
Reg. No. 36,848  
KMK:BRD:sab

